

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : O'Brien, Timothy J. et al.
Serial No. : Unassigned
Filing Date : September 27, 2001
For :
Group Art Unit : Unassigned
Examiner : Unassigned

**REPEAT SEQUENCES OF THE CA125 GENE AND THEIR USE
FOR DIAGNOSTIC AND THERAPEUTIC INTERVENTIONS**

Assistant Commissioner for Patents
Attn: Box Patent Application
Washington, DC 20231

JC821 U.S. PTO
09/965738
09/27/01

**PETITION TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION OF
APPLICATION RELATING TO THE DIAGNOSIS AND TREATMENT OF
OVARIAN CANCER (37 CFR §1.102(d))**

Applicants submit this petition to make special and respectfully request advancement of examination out of turn of the above-referenced patent application. In accordance with 37 CFR § 1.17(i), a check for the petition fee is enclosed in the amount of \$130.00.

The significance of developing new diagnostics and treatments for ovarian cancer cannot be underestimated. Ovarian cancer is a serious and under-recognized threat to women's health. Ovarian cancer kills more women than all the other gynecologic cancers combined. Ovarian cancer is the fifth leading cause of cancer death among women in the United States. Ovarian cancer occurs in 1 in 57 women, up from 1 in 70 several years ago. 14,500 women will die this year alone. More than 25,500 will be diagnosed.

Ovarian cancer is very treatable when caught early; however, the vast majority of cases are not diagnosed until too late. Only 24% of ovarian cancer is caught early primarily because ovarian cancer is difficult to diagnose. Currently, there is no reliable screening test for the early detection of ovarian cancer. Further, symptoms of this disease are often vague and easily confused with other diseases.

CA125, which is the focus of the present patent application, is an antigenic determinant located on the surface of ovarian carcinoma cells with essentially no expression in normal adult ovarian tissue. Elevated in the sera of patients with ovarian adenocarcinoma, CA125 has played a

critical role for more than 15 years in the management of these patients relative to their response to therapy and also as an indicator of recurrent disease.

CA125 has long presented problems to both clinicians and investigators because there was no definitive information on its structure and function. The present patent application seeks to overcome these problems by providing an extensive disclosure on the cloning, sequencing, and identification of the various domains of the CA125 gene. Such cloning of CA125 has not heretofore been accomplished. The present invention overcomes the disadvantages of current assays by providing multiple repeat domains of CA125 with epitope binding sites. At least one or more of any of the more than 60 repeats which have been identified can be used as a "gold standard" for testing the presence of CA125. Furthermore, new and more specific assays may be developed utilizing recombinant products for antibody production. Perhaps even more significantly, the multiple repeat domains of CA125 or other domains could also be used for the development of a potential vaccine for patients with ovarian cancer.

The recombinant CA125 of the present invention may also be used to develop therapeutic targets. Molecules like CA125, which are expressed on the surface of tumor cells, provide potential targets for immune stimulation, drug delivery, biological modifier delivery or any agent which can be specifically delivered to ultimately kill the tumor cells. Humanized or human antibodies to CA125 epitopes could be used to deliver all drug or toxic agents including radioactive agents to mediate direct killing of tumor cells. Natural ligands having a natural binding affinity for domains on the CA125 molecule could also be utilized to deliver therapeutic agents to tumor cells.

In view of the significant attributes of the present invention relating to the diagnosis and treatment of ovarian cancer, Applicants respectfully request that their petition to advance examination of the patent application be granted. Should the Examiner find that the petition requires additional information and/or supplementation, Applicants request that the undersigned Counsel be contacted as soon as possible at the telephone number listed below.

Date: September 27, 2001

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